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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,952	06/04/2001	Reinhard Zeisig	01070-032	3305

23622 7590 03/26/2003

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/873,952

Applicant(s)

Zeisig

Examiner

Gollamudi Kishore

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-18 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 11 6) ☐ Other:

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### **DETAILED ACTION**

**The amendment dated 1-28-02 and the change of address dated 2-26-02 are acknowledged.**

**Claims included in the prosecution are 9-18.**

#### ***Claim Rejections - 35 USC § 112***

**1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

**2. Claims 13, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**The chemical names of ICI 164,3384, ICI 182,780 should be recited in claim 13. Also unclear is what the 'main metabolite of tamoxiphen is. It should be identified since the claim also recites other tamoxiphen derivatives by name.**

**It is unclear whether the limitation in parenthesis is indeed the limitation as recited in claim 17.**

**The chemical name of OPP should be recited in claim 18.**

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*Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over either WO 96/11670 in combination with Jalonen (5,571,534) by itself or in further combination with Grunicke (5,770,593).

WO 96 teaches liposomal formulations containing an antineoplastic ether lipid. The liposomes further contain a phospholipid, PEG derivatized lipid and an additional antineoplastic agent (note the abstract, page 8, lines 9-23; pages 10 and 12-15; Examples and claims). What is lacking in WO is the teaching of tamoxiphen as the additional antineoplastic agent.

Jalonen discloses that anti-estrogens are poorly soluble in water and in order to give effective amounts of these compounds in cancer therapy, they are encapsulated in liposomes. Jalonen teaches tamoxiphen and other anti-estrogens (note the abstract, col. 1, line 35 through col. 2, line 12; col. 3, line 49 et seq.).

Grunicke teaches synergistic combination therapy compositions containing tamoxiphen, ether phospholipid and other antineoplastic agents (note the abstract; col. 3, lines 16 through 61; claims).

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The use of tamoxiphen or other antiestrogens as the specific antineoplastic agent in the liposomal compositions containing the ether phospholipids and the encapsulated antineoplastic agent, with the expectation of obtaining at least an additive effect would have been obvious to one of ordinary skill in the art since Jalonon teaches liposomal encapsulation of tamoxiphen to achieve effective levels of these compounds in cancer therapy. One of ordinary skill in the art would be motivated to combine tamoxiphen with the liposomal compositions of WO since Grunicke teaches combination of ether lipids and tamoxiphen has a synergistic effect.

5. Claims 9-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over either DE 44 08 011 of record or DE 41 32 345 of record or Arndt (Breast Cancer Research and Treatment, 1997) of record in combination with Jalonon (5,571,534) cited above by itself or in further combination with Grunicke cited above.

DE 44 08 011, and DE 41 32 345 each teach liposomal compositions containing an antineoplastic alkyl phospholipid, PEG modified phospholipid and cholesterol (note the abstracts, Examples and claims of each). Similarly Arndt teaches a similar liposomal composition (note the abstract and entire publication).

What is lacking in these references is the teaching of the inclusion of an additional antineoplastic agent, tamoxiphen in the liposomal compositions.

As pointed out above, Jalonon discloses that anti-estrogens are poorly soluble in water and in order to give effective amounts of these compounds in cancer therapy, they

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are encapsulated in liposomes. Jalonon teaches tamoxiphen and other anti-estrogens (note the abstract, col. 1, line 35 through col. 2, line 12; col. 3, line 49 et seq.).

Grunicke teaches synergistic combination therapy compositions containing tamoxiphen, ether phospholipid and other antineoplastic agents (note the abstract; col. 3, lines 16 through 61; claims).

The use of tamoxiphen or other antiestrogens in the liposomal compositions containing the alkyl phospholipids of DE (011), DE (345), with the expectation of obtaining at least an additive effect would have been obvious to one of ordinary skill in the art since Jalonon teaches liposomal encapsulation of tamoxiphen to achieve effective levels of these compounds in cancer therapy. One of ordinary skill in the art would be motivated to combine tamoxiphen with the liposomal compositions of WO since Grunicke teaches combination of ether lipids and tamoxiphen has a synergistic effect.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**March 4, 2003**